BARD | PERIPHERAL VASCULAR

TR-10-06-12
Rev. 1

DV&V

Diaphragmatic Flat Plate Fatigue and Corrosion Examination of the Meridian Filter

(Project # 8120)

Originator: Matt Casiraro

Keywords: Meridian, Diaphragmatic, Durability, Fatigue, Filters, 8120, ELF, Flat Plate, Electropolish, Caudal

INTRODUCTION

1.0 PURPOSE / OBJECTIVE

The purpose of this report is to describe the results of the accelerated *in-vitro* fatigue testing of the Meridian filter design under simulated physiological diaphragmatic conditions.

2.0 BACKGROUND

The Meridian Filter is identical to the Eclipse Filter with the addition of titanium (Ti Al-4V ELI) caudal anchors on the 6 arms. Three (3) of the arms have caudal anchors added to the wrist and the remaining three (3) arms have caudal anchors added to the shoulder section to improve filter caudal migration resistance.

When implanted in the inferior vena cava (IVC), the filter may be subjected to cyclic radial expansion/compression due to due to respiratory contractions. Respiratory fatigue testing is designed to simulate the physiological conditions on the filter due to the expanding and contracting of the vessel in which it is implanted. Per the FDA Guidance Document- Guidance for Cardiovascular Intravascular Filter 510(k) Submissions [4.2.1], the filter durability must be proven safe *in vivo* for up to ten (10) years of implantation life. Accelerated *in-vitro* fatigue testing is conducted In order to demonstrate this in a reasonable amount of time.

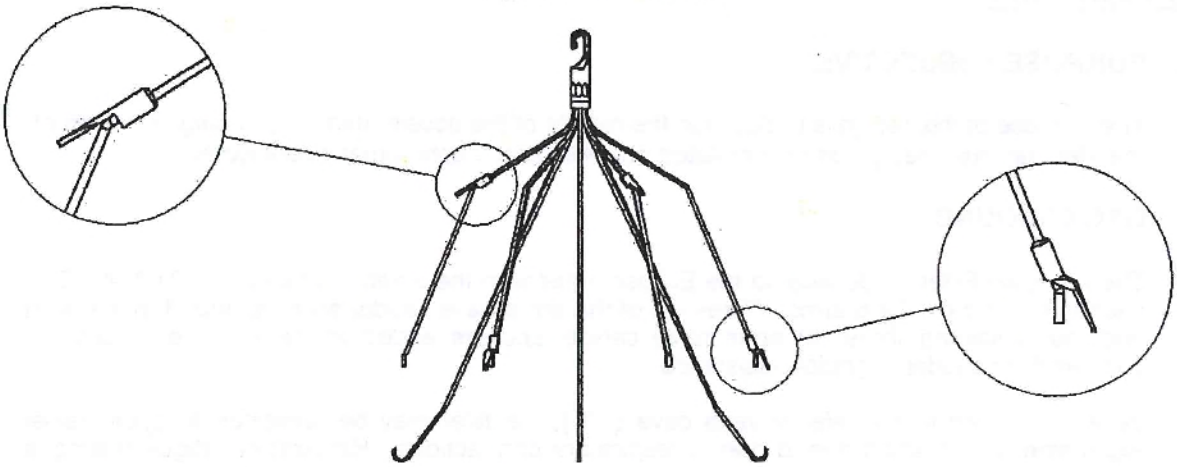
The test deflection evaluated under the protocol was based on loading parameters from published articles on fatigue testing of the stainless steel Greenfield filter (SGF) [4.5 & 4.6]. This deflection was chosen in an attempt to mimic maximal physiologic changes that could occur in a normal human Vena Cava [4.6]. Previous testing of the Eclipse filter utilizing the same deflection parameters and demonstrated that the Eclipse filter was safe up to ten (10) years of implantation.

3.0 PRODUCT/PROCESS DESCRIPTION

The Meridian Filter (Figure 1) is a blood clot trapping device designed to prevent pulmonary embolism by mechanical filtration. The filter is implanted percutaneously in the inferior vena cava (IVC) and may be used as a permanent filter. In addition, the Meridian Filter has been designed to have the ability to be percutaneously removed after implantation with minimal trauma to the IVC.

The Meridian Filter consists of twelve shape-memory Nitinol wires emanating from a central snareable tip. These twelve (12) wires form two (2) levels of filtration for emboli; the legs provide the lower level of filtration and the arms provide the upper level of filtration. Elastic hooks at the leg ends allow the filter to remain rigid and resist migration, while providing elastic deformation when the filter is percutaneously removed. Three (3) of the arms have caudal anchors welded to the wrist and remaining three (3) arms have caudal anchors welded to the shoulder to improve filter caudal migration resistance. The Meridian Filter is intended to be used in the inferior vena cava (IVC) with a diameter less than or equal to 28 mm.

Figure 1: Meridian Filter



4.0 REFERENCES

4.1 Internal References

[redacted]

[redacted]

4.2 External References

4.2.1 FDA Guidance Document- Guidance for Cardiovascular Intravascular Filter 510(k) Submissions. Document issued on: November 26, 1999.

4.2.2 CM Wayman et al., Engineering Aspects of Shape Memory Alloys, Butterworth-Heinemann Ltd, 1990, 3-20.

4.2.3 Doppman, J. Mechanism of obstruction of the infradiaphragmatic portion of the inferior vena cava in the presence of increased intra-abdominal pressure. Investigative Radiology. Vol 1: 37-53, 1996.

4.2.4 ASTM E739-91: Standard Practice for Statistical Analysis of Linear or Linearized Stress-Life (S-N).

4.2.5 Murphy, E.H., et al. Evaluation of Wall Motion and Dynamic Geometry of the Inferior Vena Cava Using Intravascular Ultrasound: Implications for Future Device Design. Journal of Endovascular Therapy. Vol 15: 349-355, 2008.

4.2.6 Murphy, E.H., et al. Volume Associated Dynamic Geometry and Spatial Orientation of the Inferior Vena Cava. Journal of Vascular Surgery. Vol 50, Number 4: 835-843, Oct 2009.

4.2.7 Osher Pais, S (1989): Percutaneous Insertion of the Greenfield Filter. AJR, 152, 933-938.

4.2.8 Bjarnason, H (1994): In Vitro Metal Fatigue Testing of Inferior Vena Cava Filters. Investigative Radiology, 29, 817-821.

4.2.9 Greenfield, L (1989): Comparison of titanium and stainless steel Greenfield vena caval filters. Surgery, 106, 820-828.

4.2.10 Surinderr S. Birring et al., Cough frequency, cough sensitivity and health status in patients with chronic cough, Respiratory Medicine, Vol. 100, Issue 6, p. 1105-1109.

4.2.11 A. Guyton, Medical Physiology, W.B. Saunders, Sixth Edition, p.483.

4.2.12 E. Marieb, J. Mallatt, Human Anatomy, Benjamin/Cummings, Second Edition, p.552.

4.2.13 A.J. Vander, J.H. Sherman, D.S. Luciano, Human Physiology, McGraw-Hill, Third Edition, p.340.

MATERIALS AND METHODS

5.0 MATERIALS

A total of twelve (12) Meridian Filters were tested, see Table 1 for detailed sample quantities and description of test samples.

This sample size was chosen based on ASTM E739-91; this standard recommends 12-24 samples for reliability fatigue testing and the capacity of the test equipment. The highest stress point on the filter occurs in the neck area where the arms exit the snare tip. During flat

plate loading, two (2) of the filter arms (arms perpendicular to the deflection) experienced the highest strains. Based on the twelve (12) filters tested, this equated to twenty-four (24) high stress points.

Table 1: Sample Quantity and Description of Test Samples

Qty	Lot #	Sterilization #	Ship Cond. #	Sample Description	Sample Numbers
12	ESM-06-10-072	CV102560-2, CV102583-4 (2X EO Cycle 7)	N/A	Meridian Filter	Samples were labeled 1 - 12

5.1 Manufacture

The Meridian Filter samples were manufactured and packaged according to the ESM packets attached to this report (ESM-06-10-072). The ESM packet can be found in Appendix 13.3.

5.2 Sterilization

[redacted]

5.3 Ship Conditioning

[redacted]

5.4 Environmental Conditioning

[redacted]

6.0 EQUIPMENT

Table 2: Equipment List			
Equipment Description	Asset Number	Calibration date	Calibration Due Date
[redacted]			

All equipment was within calibration at the time of testing.

7.0 TRAINING

All individuals responsible for performing tests or analyses described in TP-10-06-12 were trained on the protocol, test methods, and procedures. All training records are located in Appendix 13.2.

8.0 DEVIATIONS

There were no deviations from the test protocol (TP-10-06-12).

RESULTS AND RECOMMENDATIONS

9.0 RESULTS

Table 3: Result Summary Table for Meridian Respiratory Fatigue Samples						
	Acceptance Criteria		Characterization (Not Acceptance Criteria)			
Sample ID	Filter Fractures (Pass/Fail)	Filter Corrosion (Pass/Fail)	Shoulder Anchor: 5.0 lb. Proof Load supported? (Yes/No)	Wrist Anchor: 5.0 lb. Proof Load supported? (Yes/No)	Arm: 5.0 lb. Proof Load supported? (Yes/No)	Leg: 5.0 lb. Proof Load supported? (Yes/No)
1	[redacted]					
2						
3						

4	[redacted]
5	
6	
7	
8	
9	
10	
11	
12	

Note*: See data analysis section 10.3 for discussion

All test parameters were within acceptable ranges for the duration of the test.

Table 4. Test Parameter Ranges

	Total Deflection (mm)*	Tube Diameter (mm)*	Test Frequency(Hz)	Temperature (C°)	pH
Min	[redacted]				
Max					

Note*: The total deflection and tube diameter were calculated based upon the software reading and the tube diameter at setup (i.e. 20mm and delfection of +5.00mm – 5.50mm).

[redacted]

10.0 DATA ANLYSIS AND DISCUSSION

10.1 Structural Integrity

[redacted]

[redacted]

10.2 Examination of Corrosion Resistance

[redacted]

10.3 Examination of Weld Strength following Cycling

[redacted]

[redacted]

Table 5: Comparison of Sample 3 Wrist to Similar Failure Modes Exhibited in Destructive Tensile Testing	
TR-10-06-12 sample 3 wrist weld side 1	TR-10-06-12 sample 3 wrist weld side 2

[redacted]

10.4 **FEA Analysis**

[redacted]

Table 6: Summary of FEA Analysis (Arm with Anchor)

Component	[redacted]
Arm with Wrist Anchor	
Arm with Shoulder Anchor	

Table 7 displays the respective stresses, mean stresses, alternating stresses, Goodman fatigue values, and factors of safety for the anchors analyzed separately from the arm.

Table 7: Summary of FEA Analysis (Anchor Only)		
Component	[redacted]	
Wrist Anchor		
Shoulder Anchor		

Based on the preceding fatigue analysis utilizing an applied load of [redacted] on the Meridian Filter after deployment into [redacted] there is a considerable fatigue safety, as the factor of safety at each component analyzed is significantly high.

11.0 CONCLUSION

All twelve (12) Meridian Filter samples were structurally intact; there were no fractures at 4,000,000 cycles. In addition, there was no visible presence of corrosion on any of the Meridian Filter samples. Thus, the acceptance criteria defined in TP-10-06-12 has been met. Based on the data presented in this report, the diaphragmatic *in-vitro* fatigue testing results demonstrate the long-term *in vivo* safety of the filter at a duration of up to ten (10) years.

12.0 RECOMMENDATIONS

The laser welding process should be validated and process controls should be further explored.

13.0 APPENDICIES

13.1 Data Sheets
13.2 Employee Training Documentation
13.3 ESM Packet 06-10-072
13.4 Sterilization Router
13.5 Post fatigue filter images / memo

13.0 REVISION HISTORY

REVISION NUMBER	CR NUMBER	DESCRIPTION/ORIGINATOR
0	BPV TP/TR [XXXX]	Introduction/ Matt Casiraro

Appendix 13.1: Data Sheets